

Remarks

Claims 1-7 and 26-47 were pending in the subject application. By this Amendment, claims 21, 23, 39, and 41 have been amended, and claim 2 has been cancelled. The undersigned avers that no new matter is introduced by this amendment. Accordingly, claims 1, 3-7, and 19-47 are currently before the Examiner for consideration. Entry and consideration of the amendments presented herein is respectfully requested.

A supplemental Information Disclosure Statement (IDS) is submitted herewith for the Examiner's consideration in the subject application. The applicants respectfully request that the references listed in the IDS be considered and made of record.

Claim 2 is objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of claim 30. By this Amendment, the applicants have cancelled claim 2, rendering this objection moot. Reconsideration and withdrawal of the objection is respectfully requested.

Claims 1, 3-7, and 19-29 have been rejected under 35 U.S.C. §112, first paragraph, as lacking sufficient written description. The Office Action indicates that the subject specification does not describe a representative number of species of genetic elements that would constitute a carbohydrate responsive mRNA instability element.

The applicants respectfully submit that the subject specification does provide a sufficient written description of the genus of carbohydrate responsive mRNA instability elements as currently claimed. The nucleic acid sequence of SEQ ID NO:9, which was obtained from rat vascular smooth muscle cells, is provided as an exemplified carbohydrate responsive mRNA instability element. However, given the benefit of the subject specification, one of ordinary skill in the art can readily determine other homologous nucleic acid sequences that function as carbohydrate responsive mRNA instability elements, based upon sequence similarity. Submitted herewith as Exhibit A is a sequence alignment of the mRNA of nucleotides 2-39 of SEQ ID NO:9 produced using the National Center for Biotechnology Information's (NCBI) Basic Local Alignment Search Tool (BLAST) server. The sequence comparison demonstrates that the nucleic acid sequence of SEQ ID NO:9 is highly conserved across species (*e.g.*, human, mouse, rat, rabbit, bovine). Such sequence databases are publicly available and readily utilized by those of ordinary skill in the art.

“To comply with the description requirement of 35 U.S.C. §112, first paragraph . . . all that is required is that the application reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed . . .” *Forssmann v. Matsuo*, 23 USPQ 2d 1548, 1550 (B.P.A.I. 1992), *aff’d*, 991 F. 2d 809 (Fed. Cir. 1993). Thus, the applicants respectfully submit that the subject specification would convey to one having ordinary skill in the art that the applicants had possession of the concept of what is claimed.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

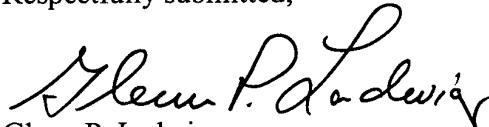
Claims 21, 23, 39, and 41 have been rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 5,795,961 (Wallace *et al.*). The Office Action indicates that the Wallace *et al.* patent discloses a nucleotide sequence (SEQ ID NO:5) that would hybridize to the nucleotide sequence of SEQ ID NO:9, which is recited in claims 39 and 41 of the subject application. By this Amendment, the applicants have amended claims 21, 23, 39, and 41 to recite that the probe or primer is capable of hybridizing to at least 15 consecutive bases of a polynucleotide encoding a carbohydrate responsive mRNA instability element. Support for this amendment can be found, for example, within claim 11 of the subject application, as originally filed. As is evident from the sequence alignment attached with the Office Action, SEQ ID NO:5 of the Wallace *et al.* patent does not contain 15 consecutive bases that hybridize with SEQ ID NO:9 of the subject invention. Thus, the Wallace *et al.* patent does not teach or suggest the invention as currently claimed. Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Glenn P. Ladwig
Patent Attorney
Registration No. 46,853
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: Saliwanchik, Lloyd & Saliwanchik
A Professional Association
2421 NW 41st Street, Suite A-1
Gainesville, FL 32606-6669

GPL/mv

Attachments: Exhibit A
Supplemental Information Disclosure Statement

Exhibit A**SEQUENCE ALIGNMENT RESULTING FROM BLAST SEARCH**

| | |
|------------------------|--------------------------------------|
| SEQ ID 9: | AACUCUGAAUUUUAAAACCGAAGUCAAGAGCUAGUA |
| Human PKC β II: | AACUCUGAAUUUUAAAACCGAAGUCAAGAGCUA |
| Rat PKC β II: | AACUCUGAAUUUUAAAACCGAAGUCAAGAGCUA |
| Mouse PKC β II: | AACUCUGAAUUUUAAAACCGAAGUCAAGAGCUA |
| Rabbit PKC β II: | AACUCUGAAUUUUAAAACCGAAGUCAAGAGCUA |
| Bovine PKC β II: | AACUCUGAAUUUUAAAACCGAAGUCAAGAGCUA |

The NCBI accession numbers, citations, parameters, and results corresponding to the BLAST search are provided below:

1. *Homo sapiens* protein kinase C beta-II type (PRKCB1) mRNA, complete cds; NCBI accession number M13975.1; Coussens, L. *et al.*, *Science* 233 (4766):859-866 (1986)

Score = 69.9 bits (35), Expect = 2e-10

Identities = 35/35 (100%)

Strand = Plus / Plus

2. *Rattus norvegicus* mRNA for protein kinase C type II; NCBI accession number X04440; Ono, Y. *et al.*, *FEBS Lett.* 206(2):347-352 (1986)

Score = 69.9 bits (35), Expect = 2e-10

Identities = 35/35 (100%)

Strand = Plus / Plus

3. *Mus musculus* mRNA for protein kinase C beta-II; NCBI accession number X53532.1; Tang, Y. M. and Ashendel, C.L., *Nucleic Acids Res.* 18(17):5310 (1990)

Score = 61.9 bits (31), Expect = 4e-08

Identities = 34/35 (97%)

Strand = Plus / Plus

4. *Oryctolagus cuniculus* mRNA for protein kinase C alpha (PKC-alpha); NCBI accession number X04793; Ohno, S. *et al.*, *Nature* 325(7000):161-166 (1987)

Score = 61.9 bits (31), Expect = 4e-08

Identities = 34/35 (97%)

Strand = Plus / Plus

5. *Bos taurus* beta type protein kinase C mRNA complete cds; NCBI accession number M13974; Coussens, L *et al.*, *Science* 233(4766):859-866 (1986)
Score = 61.9 bits (31), Expect = 4e-08
Identities = 34/35 (97%)
Strand = Plus / Plus